DEPARTMENT OF HEALTH & HUMAN SERVICES
New York District

Food & Drug Administration
300 Pearl Street, Suite 100
Buffalo, NY 14202

April 20, 2001

WARNING LETTER NYK 2000-63

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Alan B. Foster, M.D.
Chief Radiologist
St. Joseph's Imaging Associates
4109 Medical Center Drive
Fayetteville, New York 13066

RE: Facility ID Number 139360

Dear Dr. Foster:

Your facility was inspected on April 16, 2001 by a representative of the New York State Department of Health, acting on behalf of the Food and Drug Administration (FDA). This inspection revealed serious regulatory problems involving the mammography at your facility.

Under a United States Federal law, the Mammography Quality Standards Act of 1992, your facility must meet specific requirements for mammography. These requirements help protect the health of women by assuring that a facility can perform quality mammography. The inspection revealed the following repeat Level 2 findings at your facility:

- ***Failure to produce documents verifying the radiological technologist [redacted] met the continuing education requirement of having taught or completed a minimum of 15 CME credits in a 36-month period.***

- ***Failure to produce documents verifying the radiological technologist [redacted] met the continuing education requirement of having taught or completed a minimum of 15 CME credits in a 36-month period.***

The specific problems noted above appeared on your MQSA Facility Inspection Report which was issued to your facility at the close of the inspection. These problems are identified as repeat Level 2 because they identify a failure to meet a significant MQSA requirement and they indicate a failure of your facility to implement permanent correction of problems found during your previous inspection.

Because these conditions may be symptomatic of serious underlying problems that could compromise the quality of mammography at your facility, they represent violations of the law which may result in FDA taking regulatory action without further notice to you. These actions include, but are not limited to, placing your facility under a Directed Plan of Correction; charging your facility for the cost of on-site monitoring; assessing civil money penalties up to $10,000 for each failure to substantially comply with, or each day of failure to substantially comply with MQSA standards; suspension or revocation of your facility's FDA certificate; obtaining a court injunction against further mammography.

It is necessary for you to act on this matter immediately. Please explain to this office in writing within fifteen (15) working days from the date that you receive this letter each step your facility is taking to correct these violations and to prevent the recurrence of similar violations. Please submit your response to the attention of Lisa M. Utz, Compliance Officer, U.S. Food and Drug Administration, 300 Pearl Street, Olympic Towers, Suite 100, Buffalo, New York 14202.

Finally, you should understand there are many FDA requirements pertaining to mammography. This letter pertains only to findings of your inspection and does not necessarily address other obligations you have under the law. You may obtain general information about all of FDA's requirements for mammography facilities by contacting the Mammography Quality Assurance Program, Food and Drug Administration, P.O. Box 6057, Columbia, Maryland 21045-6057 (1-800-838-7715), or through the Internet at http://www.fda.gov.

Sincerely,

Edward W. Thomas
Acting District Director